

REMARKS

Claims 1-7 are pending.

Applicants would like to thank the examiner for conducting a telephone interview with Applicants' representative on September 8, 2008. The examiner agreed to reconsider the rejection of "non-hygroscopic" based on the guidance provided in the specification in view of the knowledge of one of ordinary skill in the art, as set forth in detail below. The examiner also indicated that removal of the ethanol content limitation from claim 7 should overcome the indefiniteness rejection of that claim.

The examiner also agree to reconsider the 102 and 103 rejections in view of Applicants' previous response, as further explained during the interview and as set forth below.

Rejections Under 35 USC 112, Second

The specification describes the invention as "non-hygroscopic". *See* Abstract. The specification also describes the invention as "a new ethanolate of azithromycin that is less hygroscopic than azithromycin monohydrate." *See* col. 1, ll. 61-63. Thus, Applicants submit that the claim term "non-hygroscopic" would be well understood by one of ordinary skill in the art, in view of the specification, as meaning "less hygroscopic than azithromycin monohydrate." The specification provides further guidance by providing, for example, Fig. 1, which clearly shows a non-hygroscopic embodiment of the invention as less hygroscopic than the monohydrate.

Although the hygroscopicity of the invention is not zero, one of ordinary skill in the art would understand that non-hygroscopic does not mean zero hygroscopicity. First, it is clear from the specification, e.g., Figure 1, that the invention does not have zero hygroscopicity. Second, the term "non-hygroscopic" is often used in the art to mean a relatively small, non-zero amount of hygroscopicity. *See, e.g.*, US 6,696,600 (col. 5, l. 37) and US 6,583,274. Thus, defining "non-hygroscopic" as "less hygroscopic than azithromycin monohydrate" is not inconsistent with how the term is used in the art.

Rejections Under 35 USC 102 and 103

The Office has rejected all of the pending claims, claims 1-7, as anticipated or obvious in view of the Chinese patent (CN 1161971) (translated). Applicants respectfully traverse.

The Chinese patent states that its invention is a crystalline form of azithromycin that is not a dihydrate. Although the Chinese patent does not describe the unit cell of the crystalline form it obtained, the specification makes it clear that only one form was obtained and that that form was obtained by crystallizing from “a mixture of a water-soluble organic solvent and water The water-soluble organic solvent is selected from the group consisting of ethanol, acetone, isopropanol, propanol, 1,2-propylene glycol, [etc.]”. See p. 4. The Chinese specification provides two exemplary organic solvents: acetone and a mixture of acetone and ethanol.

Since the Chinese patent describes only one crystalline form of azithromycin having the specific properties set forth on pages 2-4 of the Chinese patent, this crystalline form can only be a solvate of acetone or water because these are the only solvents that are used in both examples. A solvate of ethanol is not possible from the first example. See Aronhime Declaration (previously submitted on or about February 4, 2008). Thus, none of the Examples in the Chinese patent describes the claimed ethanolate.

The Office asserts that Example 2 of the Chinese patent might inherently disclose the claimed ethanolate. “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” MPEP 2112(IV). “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not. . . . Therefore, the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product.” MPEP 2112.01(I).


Here, the Office has not met its initial burden of providing sufficient facts or technical reasoning to reasonably allege inherency. Example 2 of the Chinese patent, if taken out of context, might suggest the possibility that an ethanolate could have been formed; however, when Example 2 is read in the context of the entire disclosure, it is clear that an ethanolate could not have been formed in Example 2. Specifically, as described above, the Chinese patent implicitly states that the product of Example 2 is the same as the product of Example 1, which cannot possibly be an ethanolate. Thus, the Office has not met its initial burden to allege inherency. Applicants therefore respectfully request withdrawal of the rejections.

Applicants submit that the pending claims are in condition for allowance. The Examiner is invited to contact the undersigned at 202-220-4200 to discuss any matter regarding this application.

Respectfully submitted,

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